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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,510

11/24/2003

Richard D. Gresham

2877

4596

7590 05/25/2010  
Kimberly V. Perry  
U.S. Surgical  
A Division of Tyco Healthcare Group, LP  
150 Glover Avenue  
Norwalk, CT 06856

EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/25/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/720,510	<b>Applicant(s)</b> GRESHAM ET AL.	
	<b>Examiner</b> MICHAEL G. MENDOZA	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-26 is/are allowed.
- 6) ☒ Claim(s) 1-16 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

In view of the Appeal Brief filed on 17 December 2009, PROSECUTION IS HEREBY REOPENED.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

Art Unit: 3734

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 3, 8-10, and 31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7449011. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claim is merely broader than the patent claim. The more specific claims of the patent anticipate the broader claims of the application.

Art Unit: 3734

3. Claims 2, 4-7, 11-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, and 8-10 of U.S. Patent No. 7449011 in view of Carlson et al. 5827319. The applicant claim merely adds features absent from the patent claim. The patent fails to claim an introducer, the tubular sheath comprising a mesh, and a dilator.

4. Carlson et al. teaches an access system comprising a common introducer, tubular sheath comprising a mesh, and dilator (see figs). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include an introducer, a tubular sheath comprising a mesh, and a dilator in the system of Patent No. 7449011, since it is well known in the art for expandable access device to provide an introducer, a tubular sheath comprising a mesh, and a dilator for opening/expanding a surgical site.

***Allowable Subject Matter***

5. Claims 17-26 are allowable over the prior art of record.

6. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or render obvious the overall claimed invention of a method of using a sheath system to enable access through an opening in the body of a patient, comprising: inserting a dilation assembly, having a radially expandable sheath defining a lumen and a proximal housing defining an aperture and a first thread in the aperture; and introducing an expansion assembly, having a tubular member with an outer surface defining a second thread formed along substantially an entire length of the tubular member into the lumen of the dilation assembly to radially expand the lumen of the dilation assembly, the introducing including engaging the first thread with the second thread to axially advance the tubular member along the

Art Unit: 3734

entire length thereof through the tubular sheath; and in combination with other limitations of the independent claim.

***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zang 5971958.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./  
Examiner, Art Unit 3734

Application/Control Number: 10/720,510

Page 6

Art Unit: 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734